



Q-LINEA

Presentation Q1(21)

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Headquarters, Marketing and demo lab, Consumable production in Uppsala

Q-linea 1st quarter



Q-linea is developing disruptive solutions for faster infectious disease diagnostics, first product targeting sepsis

146 employees & consultants at first quarter end

Very positive interim results from European clinical study.

Received first commercial order for ASTar

Value SEK >8 m and 6 mth binding orders

Pre-market activities ongoing

Finalizing marketing material together with Thermo Fisher Scientific

Strong development of the portable culturing technology

Lead product ASTar®



Q-LINEA

Sepsis – a global health crisis

Time to correct treatment critical for patient outcome



Why is improved infectious disease diagnostics important?

Sepsis

Leading cause of death in U.S. hospitals¹⁾
#1 hospitalization cost in the US with over \$24bn yearly³⁾

Kills >500,000 people yearly in the EU and US²⁾
Every 3 seconds someone dies of sepsis worldwide

~50% of all patients receive inappropriate treatment
~20% dies before current diagnostic provide results

Rapid diagnostics could reduce mortality with up to 40%⁴⁾

AMR

Antimicrobial Resistance

Has been presented as
“The biggest threat to mankind”

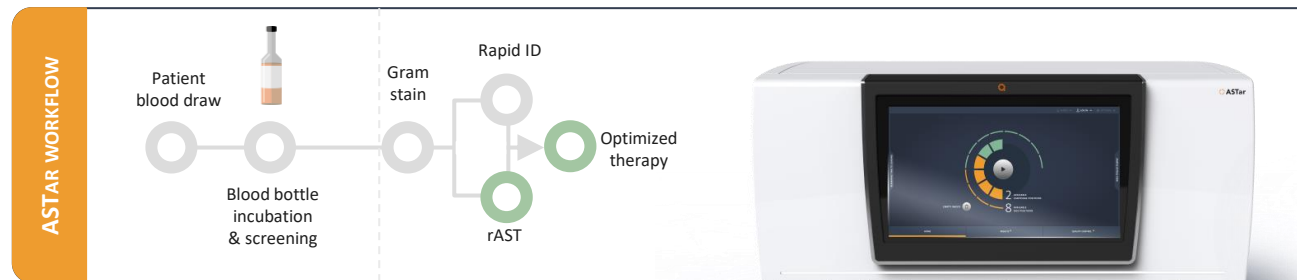
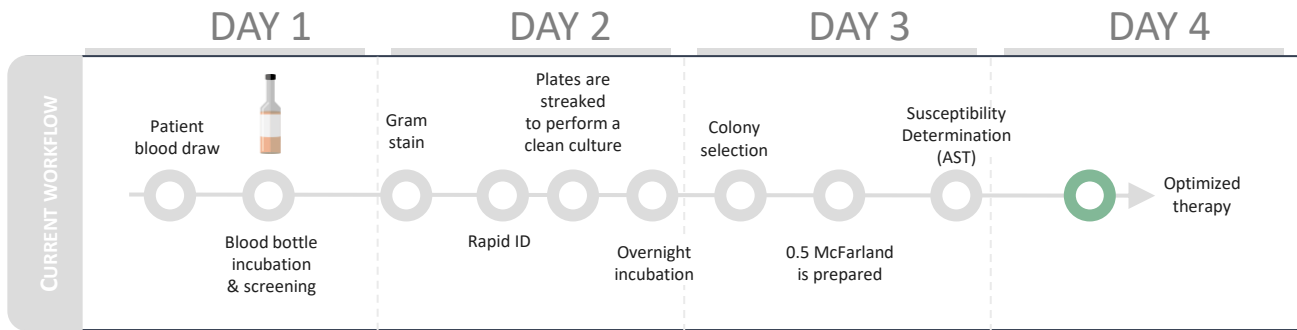
Rapid diagnostics would reduce unnecessary prescription
>65 % of all prescribed antibiotics for respiratory issues are unnecessary⁵⁾

Deaths due to AMR⁵⁾
In 2016, ~700 000 died
In 2050, 10 000 000 are expected to die from AMR if we do nothing

Source: 1. JAMA. 2014;312(1):90-92. 2. Clinical Infectious Diseases ciy342, <https://doi.org/10.1093/cid/ciy342>, , Fleischmann et al, Am J Respir Crit Care Med. 2016 Feb 1;193(3):259-72, Company estimates 3. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf>. 4. Patel et al, J Clin Microbiol. 2017 Jan; 55(1): 60–67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. Clin Infect Dis. 2013 Nov; 57(9): 1237-45. 5. Tackling drug-resistant infections: Final report and recommendations. Review on Antimicrobial Resistance. Web. 2016

Up to 40 hours faster actionable results

And requires minimal hands-on time



Time to Actionable results is what matters for septic patients

AS^{Tar} – a platform designed to save lifetimes

Easy to use

- Fully automated
- ~2 min hands-on time
- Load-and go workflow

Fast

- Results in ~6 hours
- High throughput
- 12 simultaneous samples



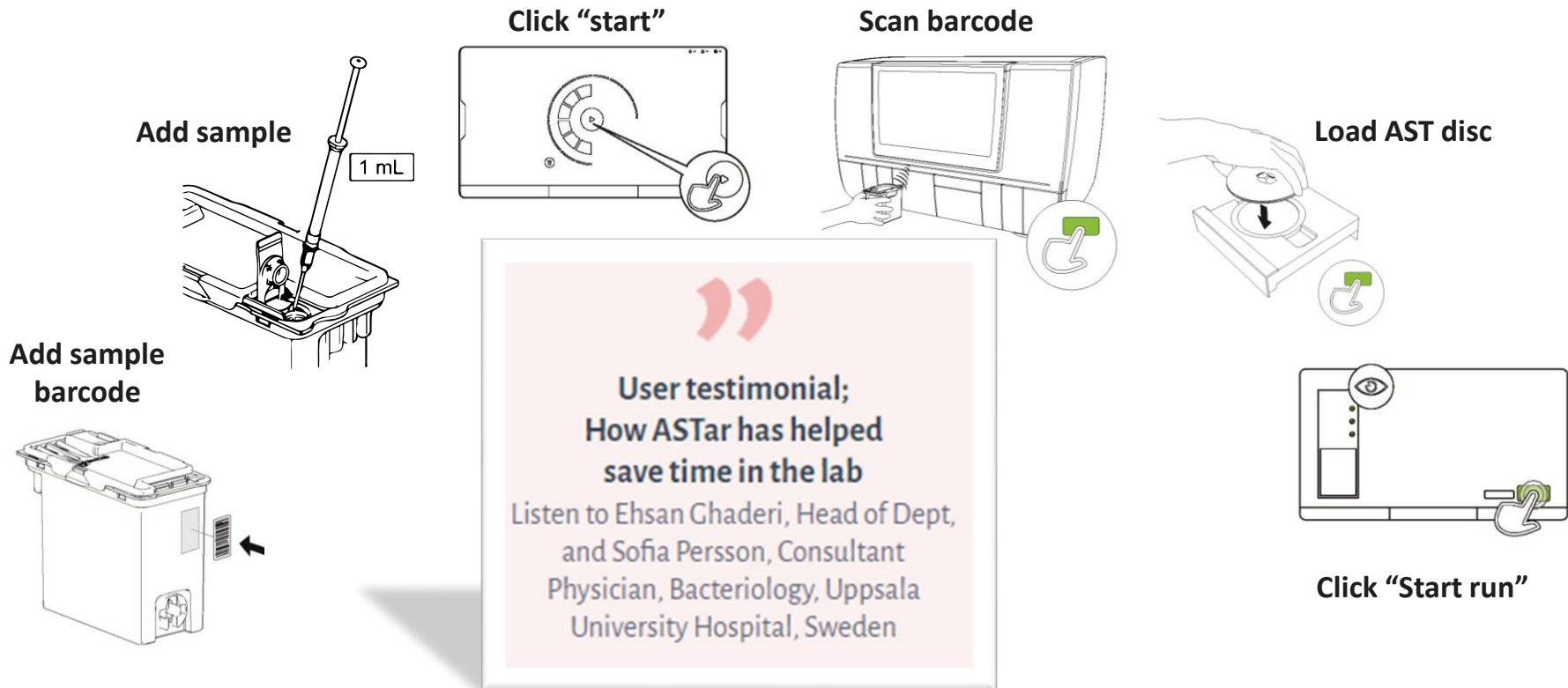
Comprehensive

- Large antibiotic panel
- Long concentration ranges
- Fastidious and non-fastidious bacteria
- Support additional samples (*e.g.* urine)

Accurate

- True MIC results
- High reproducibility

ASTar enables anyone at the lab to load sample anytime



Source: Company information and webpage

Health economic benefits of **24 hour** faster diagnostics

Lower mortality

Up to 40%
lower mortality rates¹⁾

Less pressure for resistance and superinfections

Up to 25%
reduction of *C. difficile*
infections²⁾

Cost savings

~\$2,500 – \$20,000
cost savings per patient³⁾



ASTar can provide **24-40** hour faster diagnostics

Source: 1) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. *Clin Infect Dis.* 2013 Nov; 57(9): 1237-45. 2) Fridkin et al, *MMWR*, 2014;63(9), 194-200. 3) Perez et al, *Arch Pathol Lab Med* 137:1247-1254, 2013, Perez et al *J Infect.* 2014 Sep;69(3):216-25, 2014, Bauer et al *Clin Infect Dis* 51:1074-1080, 2010.) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67.

Key highlights first quarter

Clinical study update

Presented strong interim results from the CE-IVD study

The indicative results indicated performance well above regulatory requirements for approval

**Essential agreement (EA) over 94%,
Categorical agreement (CA) over 97 %,**

Overall reproducibility over 99%,

Next step during the quarter is to finalize technical file for CE-IVD registration and some validation activities

Preparation for the US clinical study progressed well

Signed first site to participate in the US clinical study

EA means giving the same result as the reference method on the concentration of antibiotics that kill or inhibit bacterial growth.

CA means giving the same classification of the bacterium within one of three groups (S.I.R) with respect to susceptibility to antibiotics.

Key highlights first quarter

Received first order from Thermo Fisher Scientific

Value of first order > 8 million SEK

Structure with 6-month binding orders

Pre-payment for part of binding order

Marketing message and material




Q-linea and Thermo Fisher Scientific work closely together to prepare and finalize materials to support the launch of ASTar

Training ongoing

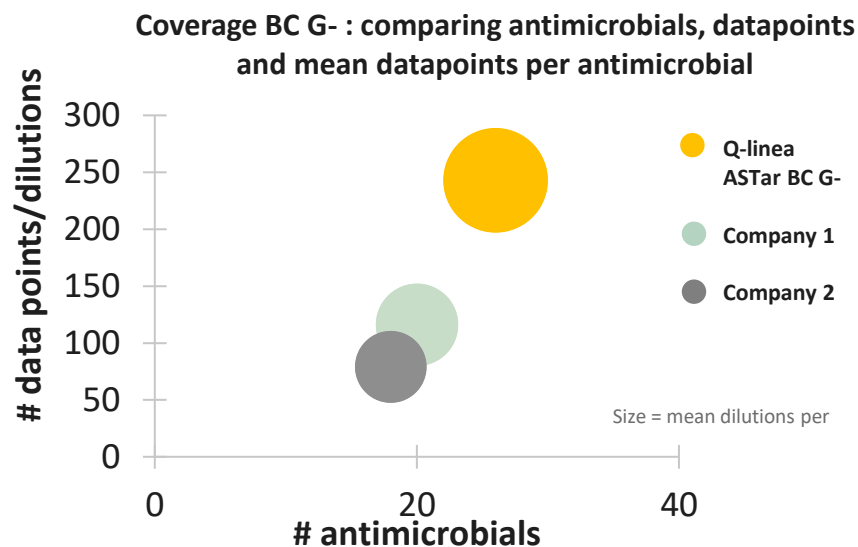
Q-linea continued and escalated training activities of Thermo Fisher Scientific sales- and service personnel

Key highlights after period end

Q-linea achieves CE-IVD for ASTar with excellent results

FDA and ISO requirements ^{1,2)}		
Essential agreement = Same MIC value as reference		
FDA	ISO	Q-LINEA 
89.9%	90%	94.7%³
Categorical agreement = Correct treatment recommendation		
FDA	ISO	Q-LINEA 
89.9%	90%	97.6%³
Reproducibility		
FDA	ISO	Q-LINEA 
95%	95%	99.6%³

The ASTar® Instrument and ASTar® BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria⁶. The analysis also **delivers true MIC results**.



Source: 1) ISO 20776-2, Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices: - Part 2: Evaluation of performance of antimicrobial susceptibility test devices 2) Guidance for Industry and FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009, FDA document number 631.3 3) Company results from CE-IVD clinical study for BC G-, Gram negative antibiotic panel 2020-05-04 6) Based on commercially available systems market overview May 2021

Full speed ahead with commercial activities



Strong interest from customers to evaluate ASTar

Ongoing activities

- Pre-market activities ongoing at full speed
- Training of personnel ongoing
- Marketing material in final preparation

Staged launch for long-term success

- First evaluation customers in the planning
- After evaluation of key customers, we aim to push for second stage launch

The effects of the Corona pandemic on Q-linea

During first quarter we have seen slight effects of the Corona pandemic

Q-linea has seen a slight increase in sickness absence, directly as well as indirectly and the employees, whose duties allow, work from home.

So-far no major changes in timelines du to Corona/Covid-19.

Future possible effects of the Corona pandemic

The timeframe of the planned clinical study, where, for example the situation in the USA can be decisive in case the hospitals are tied up with activities related testing of Coronavirus and covid-19.

The situation may also affect the commercial activities in the launch phase for both Q-linea and the partner Thermo Fisher Scientific.

Expense levels and financing strategy linked to possible delays in company activities.

We will follow the development carefully and the situation is still severe. We, as you are of course waiting for the vaccine...

Income statement first quarter

Net sales in the first quarter amounted to SEK 0 million (0.2).

Operating result totalled SEK -63.8 million (-55.9).

The company reported a loss after tax of SEK -63.2 million (-56.0).

Earnings per share, before and after dilution amounted to SEK -2.34 (-2.44).

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Source: Company information.

Balance sheet at the end of Q1

Cash and cash equivalents amounted to SEK 12.5 million (10.1)

Short-term investments in fixed-income funds SEK 106,1 million (165,7) and the current portion of non-current assets (listed bonds) SEK 82.6 million (131.0).

Non-current assets, listed bonds SEK 73.0 million (24.4).

Inventories amounted SEK 16.3 million (12.4).

Source: Company information.

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Cash flow statement first quarter

Cash flow from operating activities SEK -56.1 million (-59.1).

Decrease cash outflow from operating activities mainly due to an improvement in changes of the working capital that exceeded the larger operating result compared to the same quarter last year.

Cash flow from investing activities SEK 58.5 million (61.6).

Short-term interest funds and bonds with less than 12 months term were sold during the quarter and the company invested in bonds with over 12 months term. Investments in production facilities and equipment were less in Q1-2021 in comparison with the same quarter last year.

Cash flow from financing activities SEK -0.1 million (-0.1).

Cash and cash equivalents, Short term investments and listed bonds at the end of first quarter amounted SEK 274.2 million (331.3). The Board's assessment is that the existing working capital, as of 31 March 2021, is sufficient to cover the Company's needs for at least the next 12 months.

Source: Company information.

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Thank you

